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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 2292008

Application Number: 10/699,212
Filing Date: October 30, 2003
Appellant(s): Hennings, David. et al

James w. Geriak
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 28, 2008.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) *Status of Claims*

The statement of the status of claims contained in the brief is correct.

(4) *Status of Amendments After Final*

No amendments after final have been filed.

(5) *Summary of Claimed Subject Matter*

The summary of claimed subject matter contained in the brief is correct.

(6) *Grounds of Rejection to be Reviewed on Appeal*

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

NEW GROUNDS OF REJECTION

Claims 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Sinofsky and Dew et al. Goldman et al ('084) teach a method as claimed, including the use of tumescent anesthesia (see Abstract, second through fourth sentences and column 4, lines 43-60); heating the vessel wall to cause it to assume compressed dimensions, i.e. shrink (see Abstract, fifth and sixth sentences); moving the device in the vein to treat a larger segment thereof (Abstract, seventh sentence); and providing temperature sensors at the site (Abstract, last sentence); in the method of Goldman, the vein may be either partially or completely collapsed (see column 2, lines 41-65); this is achieved by applying sufficient thermal energy to shrink the tissue (see column 3, lines 52-56); and also involves removing a significant amount of blood from the area (column 3, lines 61-67); and that a laser may be used to provide the heating energy (see column 7, lines 53-59), but do not specify a wavelength. Sinofsky teaches the notorious nature of the high absorption of infrared wavelengths in the art (see column 4, lines 47-65). Dew et al teach the desirability of using 1.32 micron radiation to treat tissue (see column 5, lines 41-65) and the production of the 1.32 micron wavelength with an Nd:YAG laser (see column 6, lines 11-28). It would have been obvious to the artisan of ordinary skill to employ the wavelength of Dew et al produced by the laser of Dew et al in the method of Goldman et al ('084), since Goldman et al ('084) teach no particular wavelength, and since the wavelength of Dew can destroy (denature) the proteins, but allow near normal tissue to take it's place (see Dew et al column 11, lines 37-44), and since this wavelength is highly absorbed by tissue and water, as taught by Sinofsky, thus producing a method such as claimed.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Listing of Evidence Relied Upon

The following is a listing of the prior art of evidence (e.g. patents, publications Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

Number (Title)	Name	Date
4,854,320	Dew et al	August 8, 1989
5,196,004	Sinofsky	March 23, 1993
5,207,672	Roth et al	May 4, 1993
6,258,084	Goldman et al	July 10, 2001
WO 92/17243	Conn et al	October 15, 1992
WO 93/15664	Makower et al	August 19, 1993

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 2, 6, 7, 25, 35-38, 40, 41, and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Sinofsky and Dew et al. Goldman et al ('084) teach a method as claimed, including the use of tumescent anesthesia (see Abstract, second through fourth sentences and column 4, lines 43-60); heating the vessel wall to cause it to assume compressed dimensions, i.e. shrink (see Abstract, fifth and sixth sentences); moving the device in the vein to treat a larger segment thereof (Abstract, seventh sentence); and

providing temperature sensors at the site (Abstract, last sentence); in the method of Goldman, the vein may be either partially or completely collapsed (see column 2, lines 41-65); this is achieved by applying sufficient thermal energy to shrink the tissue (see column 3, lines 52-56); and also involves removing a significant amount of blood from the area (column 3, lines 61-67); and that a laser may be used to provide the heating energy (see column 7, lines 53-59), but do not specify a wavelength. Sinofsky teaches the notorious nature of the high absorption of infrared wavelengths in the art (see column 4, lines 47-65). Dew et al teach the desirability of using 1.32 micron radiation to treat tissue (see column 5, lines 41-65). It would have been obvious to the artisan of ordinary skill to employ the wavelength of Dew et al in the method of Goldman et al ('084), since Goldman et al ('084) teach no particular wavelength, and since the wavelength of Dew can destroy (denature) the proteins, but allow near normal tissue to take its place (see Dew et al column 11, lines 37-44), and since this wavelength is highly absorbed by tissue and water, as taught by Sinofsky, thus producing a method such as claimed.

Claims 3-5, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Sinofsky and Dew as applied to claims 1, 2, 6, 7, and 25 above, and further in view of Roth et al. Roth et al teach employing pull back rate as claimed, noting that the desired rate is dependent on the laser energy (see column 15, lines 24-50). It would have been obvious to the artisan of ordinary skill to employ a pull back as claimed, since these are known in the art and provide no unexpected result and to initiate pulling prior to energy application, since the problem of tissue adhesion is notorious in the art official notice of which is hereby taken, thus producing a method such as claimed.

Claims 8 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Sinofsky and Dew et al as applied to claims 1, 2, 6, 7, and 25 above, and further in view of Conn et al. Conn et al teach a diffusing tip as claimed. It would have been obvious to the artisan of ordinary skill to employ a tip as taught by Conn et al, since this would provide a uniform distribution of light and would prevent over or under treatment of tissue different areas of tissue (see page 2, first full paragraph), thus producing a method such as claimed.

Claim 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldman et al ('084) in combination with Sinofsky and Dew et al as applied to claims 1, 2, 6, 7 and 25 above, and further in view of Makower et al. Makower et al teach controlling the heating of tissue using infrared sensing (see the paragraph spanning pages 15 and 16). It would have been obvious to the artisan of ordinary skill to employ the temperature sensor of Makower et al in the method of Goldman et al ('084) since these are equivalents, as taught by Makower et al, thus producing a method such as claimed.

Claim 14-17 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in combination with Roth et al and Dew et al. Makower et al teach a device as claimed (see page 13, second full paragraph for the fiber and introducer; page 20, first full paragraph for the means for administering anesthesia; and the thermal sensor is disclosed at the paragraph spanning pages 15 and 16, as above) except the particular laser wavelength and the pull back mechanism. Dew et al teach a wavelength as claimed for treating tissue. Roth et al teach a pull back mechanism providing the claimed rate. It would have been obvious to the artisan of ordinary skill to employ the wavelength of Dew et al in the device of Makower et al,

since Makower et al teach the use of an Nd:YAG laser, which necessarily produces this radiation, as taught by Dew et al and to employ the pull back mechanism of Roth et al, since this enables uniform treatment along the surface, as taught by Roth et al, thus producing a device such as claimed.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in combination with Dew et al and Roth as applied to claims 14-17 and 20-23 above, and further in view of Conn et al. Conn et al teach a diffusing tip on an introducer for a fiber (see figure 5 and the paragraph spanning pages 14 and 15). It would have been obvious to the artisan of ordinary skill to include the diffuser of Conn et al in the device of Makower et al, since this reduces problems due to breakage, as taught by Conn et al, thus producing a device such as claimed.

(10) Response to Argument

Preface

Appellants have three main points of argument:

a) Only the preferred embodiment of using RF energy to treat the varicose vein is enabled, while the secondary embodiment of using laser energy to provide the ligation of the vein is not enabled;

b) The remaining references with which Goldman et al is combined do not teach the treatment of varicose veins; and

c) Appellants feel the examiner has refused to consider the evidence submitted by appellants to establish non-obviousness of the claimed invention.

The examiner will note here that Appellants have devoted a portion of the Brief to discussion of the Navarro Patent, which has not been applied to the claims by the examiner. This “second guessing” of the rejection which, in appellants’ opinion, the examiner should have applied to the claims is noted, however, is of little moment with regard to the analysis of the rejections which actually have been applied to the claims, and will not be discussed further herein.

a) Goldman et al is enabled for laser application

Even though the primary embodiment of Goldman et al is related to RF, rather than laser, application to provide the desired treatment, the process Goldman et al wish to implement is clearly set forth: the method is aimed at either completely closing off (see column 2, lines 41-50) or greatly reducing, while still allowing to remain patent (see column 2, lines 51-65) the vein, or other anatomical tubular structure to be operated on; the vein is treated by applying energy to the vein wall, to shrink it (see Goldman et al column 5, lines 58-65), which energy, being applied to the vein wall, heats it and causes it to shrink (see Goldman et al column 9, lines 5-13 and column 13, lines 14-24); the device can then be pulled back to treat further portions of the vein (column 13, lines 15-30). The principles of the method having been disclosed to one of ordinary skill in the art, if it were desired to employ the laser embodiment of Goldman et al, one of ordinary skill in the art would, of necessity, look to the art of laser treatment to determine the appropriate parameters which would be required to fulfill the principles set forth in Goldman et al, e.g. providing energy to the vein wall to heat it and cause it to either shrink, or be completely occluded. Sinofsky teaches a laser device to remove plaque from blood vessels or repair defects in small diameter artery walls (see column 1, lines 36-37) and for material removal and

biological material repair (see column 2, lines 50-52), which repair can be effected by coagulation (see column 3, lines 25-28), which preferred laser wavelengths are in the range of approximately 1.4 to 2.2 microns and can be transmitted through blood (see column 4, line 47 to column 5, line 6). Sinofsky also teaches that one of ordinary skill in the art is familiar with the various calculations necessary to determine the appropriate parameters for providing a given amount of heat to the tissue being acted on (see column 10, line 50 to column 11, line 41), while these are couched in terms of the primary embodiment of vaporizing plaque, the equations could also be used to calculate the amount of heat necessary to provide tissue repair e.g. by coagulation of the tissue, as disclosed in a secondary embodiment of Sinofsky. Dew et al teaches that the extent to which tissue is heated by laser energy is dependant upon the extent to which the energy is absorbed by the tissue and notes that wavelengths that pass through blood relatively unattenuated, such as the 1.32 micron wavelength, are useful (see column 5, lines 47-65). Thus, clearly, the teachings of Goldman et al, taken with the knowledge of one of ordinary skill in the art, the use of the teachings of Dew et al and Sinofsky merely constitutes a predictable use of prior art elements according to their established functions (see *KSR International Co. v Teleflex Inc.* 82 USPQ2d 1385, 1396 (Supreme Court, 2007)).

b) The teachings of the secondary references

As the teachings of the secondary references are properly combined with Goldman et al, both because they are from the laser surgery field, which Goldman et al points to by discussing lasers, and because they deal with the removal or repair of tissue in tubular organs, which Goldman et al teach, without limitation to blood vessels per se, the fact that they do not explicitly teach the treatment of varicose veins is not a bar to their combination with Goldman et al.

c) The examiner has given due consideration to the evidence submitted by appellants

Appellants assert that the examiner has “refused to consider” the evidence proffered to establish non-obviousness. The examiner must respectfully disagree. The examiner must first point out that the contents and teachings of the articles were analyzed in the rejection mailed May 17, 2006 in the paragraph bridging pages 2 and 3 thereof. However, appellants have neglected to discuss this treatment of the submissions, instead preferring to focus on the examiner’s comment in the subsequent rejection, the final rejection mailed February 12, 2007.

It is important to note that the articles and product information were submitted with Affidavits and that all Affidavits only aver that the submissions are “true copies” of the articles or product literature which is described in the Affidavits. There is no assertion whatsoever in any Affidavit of record that the articles or product literature are in any way representative of the prior art with respect to varicose vein treatment. Instead such assertions are made only in the remarks accompanying the affidavits. This is interesting, given that these remarks bear the signature of Mr. Geriak, one of the affiants. However, as these assertions are only submitted in the form of remarks accompanying a response, they cannot be elevated to the status of evidence. As such, these remarks are noted, but do not speak to the propriety of the combination which the examiner has applied to the claims.

Next appellants admonish the examiner for the “summary refusal” to consider the evidence submitted, citing In re Sullivan. The examiner respectfully submits that the evidence, that is to say the articles and product literature per se, as well as the accompanying remarks were considered and evaluated in the rejections mailed May 17, 2006 and February 12, 2007. Thus

appellants' characterization of the examiner's actions as a "summary refusal" to consider the evidentiary submissions is simply inaccurate, and the citation of Sullivan (presumably In re Sullivan 84 USPQ2d 1034), which deals with the dismissal by the Board of Affidavit evidence that was not commensurate in scope with the claimed invention; wherein the case was returned to the examiner, and further prosecuted, with the claims being then amended to recite the invention as a pharmaceutical compound for a particular type of treatment discussed in the Affidavit evidence, then returned to the Board, which deemed the particular treatment an intended use and again did not consider the Affidavit evidence; is not on point, as it does not conform to the fact pattern herein.

D) Rejection Of Claims 1, 2, 6, 7, 25, 35-38, 40, 41, and 44-46 Are Properly Rejected Under 35 U.S.C. 103(a) As Being Unpatentable Over Goldman et al ('084) in combination with Sinofsky and Dew et al

As set forth above under a), the prior art is properly combinable and properly combined so as to establish a *prima facie* case of obviousness. Appellants characterize the disclosure of the use of a laser to heat the blood vessel wall as "no more than a throw away mention of lasers". However, this is clearly not the case. The use of a laser is clearly set forth as an equivalent alternative to the RF method more thoroughly described, as well as the resistive, microwave, ultrasound, and other types of tissue heating devices set forth in Column 7 of Goldman et al. It is a well understood point of law that "All of the disclosures in a reference must be evaluated for what they would fairly teach one of ordinary skill in the art. Thus in [citations omitted] this court affirmed rejections based on art which we concluded rendered the claimed invention obvious to

those of ordinary skill in the art despite the fact that the art teachings relied upon in all three cases were phrased in terms of a non-preferred embodiment..." (see In re Boc 148 USPQ 507).

Thus appellants' extensive discussion of the teachings of references not applied to the claims, which noted that the primary mechanism for destroying the vessel was due to the heating of the blood by the various wavelengths employed by the references not applied to the claims, is insufficient to rebut the *prima facie* case of obviousness, based on, among other things, the express teaching in Goldman et al that the tissue desired to be heated is the vein wall. Thus these arguments are not convincing.

II) Claims 3-5, 42, And 43 Are Properly Rejected Under 35 U.S.C. 103(a) As Being Unpatentable Over Goldman et al ('084) in combination with Sinofsky Dew et al and Roth et al

With regard to this rejection, appellants merely assert that the additional reference does not overcome the deficiencies of the base rejection. However, as the base rejection is not deficient, this argument is not convincing.

III) Claims 8 and 39 Are Obvious Over Goldman et al ('084) in combination with Sinofsky Dew et al and Conn et al

With regard to this rejection, appellants merely assert that the additional reference does not overcome the deficiencies of the base rejection. However, as the base rejection is not deficient, this argument is not convincing.

IV) Claims 9-13 Are Obvious Over Goldman et al ('084) in combination with Sinofsky Dew et al and Makower et al

With regard to this rejection, appellants merely assert that the additional reference does not overcome the deficiencies of the base rejection. However, as the base rejection is not deficient, this argument is not convincing.

B) Claims 14 And 18 Are Obvious Over L'Esperance in Combination With Kohavakawa and Bille et al ('340)

The arguments with regard to claim 14 are predicated on the use of a sensor, as argued with respect to claim 1, and are not convincing for the same reasons.

V) Claims 14-17 And 20-23 Are Obvious Over Makower et al in Combination With Roth et al, and Dew et al

With regard to the combination involving Makower et al Roth et al and Dew et al, appellants argue that none of the reference deal with the intended use of the device. The examiner respectfully notes that to render an apparatus claim obvious, it is merely necessary that the examiner provide a *prima facie* case of obviousness for the structure claimed, not the method envisioned by appellants. As set forth above, Makower et al teach a device including an introducer, an optical fiber and a means that can be used to administer anesthetic. Since Makower et al provide no wavelength information, one of ordinary skill in the art would be motivated to employ the versatile laser of Dew et al, which could not only provide the main wavelength suggested by Roth et al, but also the 1.32 micron wavelength that could be used to seal the holes discussed in the first full paragraph of page 16 of Makower et al, which would further reduce the chance of infection therefrom.

Appellants also postulate that a pull back mechanism is incompatible with the Makower device, which includes a locking mechanism. However, a careful reading of the Makower et al

reference reveals that the locking mechanism only locks the cannula, as can be seen by the disclosure that the fiber can be completely removed and reinserted while the cannula is locked in place (see Makower et al, page 20, first full paragraph), thus no incompatibility exists, and the pull back device would allow for the treatment of a length of the prostate without removing and re-situating the cannula. Thus this argument is not convincing

B) Claim 19 Is Obvious Over Makower et al in Combination With Roth et al, Dew et al, and Conn et al

With regard to this combination, appellants have argued that none of the references of the base combination call for a diffuser. However, since one of the many embodiments of Makower et al involves photodynamic therapy (see Makower et al, page 20, second sentence) and the diffuser of Conn et al may be employed for photodynamic therapy, (see page 1, the first sentence under "BACKGROUND AND SUMMARY OF THE INVENTION") this argument is not convincing.

Appellants have requested an affidavit from the examiner with respect to the problem of tissue adhesion. However, given that the official notice was taken in the very first office action, in July of 2004, and since appellants have received four office actions in the interim, the request is not seasonable. Even assuming, arguendo, that the request was seasonable, this appears to be a moot point, since Goldman et al specifically teach the use of a pull back mechanism.

With regard to the statistical significance of the number of articles drawn to the treatment of varicose veins, the examiner submits that the dozens of articles referenced in the bibliographies of the submitted articles provide an indication of the amount of literature that

exists concerning this subject. The examiner would venture that each of these dozens of articles would cite other articles in the field. If appellant has knowledge to the contrary, appellants may submit an affidavit to the effect that this literature is the sum total of all literature in the field of varicose vein treatment.

(11) Related Proceedings Appendix

NONE

(12) Conclusion

It is the examiner's firm opinion that the appealed claims are not patentable for the reasons argued above. Appellant has presented no convincing argument as to why the rejections set forth above are not obvious or proper. Therefore, it is respectfully submitted that the final rejection be affirmed.

This examiner's answer contains a new ground of rejection set forth in section (9) above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of

rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) Maintain appeal. Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

David Shay

/david shay/
Primary Examiner, Art Unit 3735

November 6, 2008

Conferees

/Charles A. Marmor, II/
Supervisory Patent Examiner, Art Unit 3735

/Marc Jimenez/
TQAS TC 3700

David Shay

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/DONALD HAJEC/

Director, Technology Center 3700

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